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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
SAMALA, JAGADISHWAR RAO	
ART UNIT	PAPER NUMBER
1618	

MAIL DATE	DELIVERY MODE
08/05/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/644,333	DISSE, BERND	
	Examiner	Art Unit	
	JAGADISHWAR R. SAMALA	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 May 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *9,11-23 and 25-32* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *9,11-23 and 25-32* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

RCE Acknowledged

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 05/13/2008 has been entered.

Status of Application

2. Acknowledgement is made of amendment filed on 02/29/2008. Upon entering the amendment, the claims 1-8, 10 and 24 are cancelled and claim 9 is amended. Accordingly, claims 9, 11-23 and 25-32 are pending and presented for examination.

Response to Arguments

3. Applicant's arguments filed on 02/29/2008 have been considered but they are moot in view of the new ground(s) of rejection. To make better flow, upon further consideration, a new ground(s) of rejection is made as follow.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 9, 11-15, 31 and 32 are rejected under 35 U.S.C. 102(b) as being anticipated by Maesen et al (European Respir. J, 8, 1506-1513, 1995).

Maesen et al discloses inhaled tiotropium bromide has a long bronchodilator activity in patients with COPD. And discloses that inhaled single doses of 10-80 µg tiotropium bromide and placebo, formulated in lactose powder capsules produced significant improvements in FEV1, FVC, peak expiratory flow rate and forced mid-expiratory flow. The bronchodilator response was almost immediate, and in this population of patients with COPD, tiotropium bromide was found to be a safe and long-acting bronchodilator, demonstrating a clear dose-response relationship following single dose administration (see abstract). Furthermore, Maesen discloses the inhaled tiotropium bromide provided complete protection against methacholine-induced bronchoconstriction for 72 hrs.

Thus, all the critical elements required by the instant claims are well taught by the reference and all the claims are anticipated.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

5. Claims 9, 11-23 and 25-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Maesen et al (European Respir. J, 8, 1506-1513, 1995) as applied to claim9, 11-15, 31 and 32 above, and further in view of Skupin (US 5,250,286) and Hochrainer et al (US 6,150,418).

Maesen meets the claim limitations as discussed above, but fails to include physiologically acceptable excipients therein .

Skupin discloses a method comprising administering by inhalation, an active compound, which is a vasodilator and an alpha-adrengeric blocking agent, for the treatment of symptoms of COPD, including cystic fibrosis, chronic bronchitis and emphysema or COPD where it is associated with asthma (see abstract). And also discloses that the active ingredient can be admixed with solid or liquid pharmaceutically acceptable nontoxic carriers, diluents and adjuvants, including appropriate surfactants, in order to prepare the composition for use and to aid in administration to the patient by means of a pharmaceutical deliver system for the inhalation route (an aerosol or pressurized package can be employed for this purpose). Further discloses that pharmaceutical aerosol contains the therapeutically active ingredient dissolved, suspended, or emulsified in a mixture of fluid carrier and a propellant (fluorinated hydrocarbons, such as trichloromonofluoromethane, dichlorodifluoromethane, as well as compressed gases such as nitrogen, carbon dioxide, nitrous oxide or Freon, see col. 7

lines 48-68). Furthermore, the dosage of the active ingredient can be regulated, for example, by a metering valve capable of accurately delivering a measured amount of the active ingredient (see col. 9 lines 14-18).

Hochrainer et al discloses a propellant-free, active substance concentrate used as a β_2-stimulator in inhalation therapy of respiratory diseases, particularly for the treatment of bronchial asthma (see col. 1 lines 7-10). And also discloses that the active substance concentrate may be converted, by diluting with a pharmacologically acceptable liquid which optionally contains pharmaceutical adjuvants and additives, into a pharmaceutical preparation (aerosol formulation). And excipients and additives include surfactants, complexing agents (EDTA or a salt thereof, such as the disodium salt, citric acid, nitrilotriacetic acid), antioxidants and/or preservatives (benzalkonium chloride) which prolong the duration of use of the finished pharmaceutical formulation, flovourings, vitamins, and other additives know in the prior art (see col. 3 lines 20-54).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use the single doses of tiotropium bromide, inhalation formulations and their use in the treatment of COPD, as taught by Maesen, combine it with the physiologically acceptable excipients as taught by skupin and Hochrainer, and produce the instant invention.

One of ordinary skill in the art would have been motivated to do this because Maesen teaches that the administration of tiotropium bromide was found to be a safe and long-acting bronchodilator and provides complete protection against methcholine-induced bronchoconstriction.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Conclusion

1. No claims are allowed at this time.

2. Any inquiry concerning this communication or earlier communications from the examiner should be directed to JAGADISHWAR R. SAMALA whose telephone number is (571)272-9927. The examiner can normally be reached on 8.30 A.M to 5.00 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571)272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael G. Hartley/
Supervisory Patent Examiner, Art Unit 1618

Jagadishwar R Samala
Examiner
Art Unit 1618

sjr